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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	PATWA-2	5150

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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1642

DATE MAILED: 08/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/469,606

Applicant(s)

VOLLMERS ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-37 is/are pending in the application.
- 4a) Of the above claim(s) 5-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Claims 1 and 3-37 are pending.
Claims 5-37, drawn to non-elected inventions are withdrawn from consideration.
Claim 1 has been amended.
Claim 2 has been cancelled.
Claims 1, 3 and 4 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Grounds of Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 1, 3 and 4 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Claim 2 has been cancelled.

Applicants' argue that "[c]laim 1 has been amended to recite...that the glycoprotein comprises at least one section of a human amino acid primary structure of CD55" and "the claims literally cover naturally occurring sequences and the recited glycostructure which reacts with SC-1". These arguments are found unpersuasive.

There continues to be insufficient evidence supporting Applicants' broad claims, which encompass all proteins capable of exhibiting tumor-specific glycostructure and containing the human amino acid primary structure of CD55. Furthermore, Applicants have not defined or described the structure of the said structure. Applicants' specification only supports possession of one species, which is not identified by a sequence identity number or explicitly defined by structure.

Claim Rejections - 35 USC § 102

4. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Medof et al. (J. Exp. Med. 160:1558-1578, 1984), as evidenced by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS) is maintained. Claim 2 is cancelled.

Applicants argue that the glycoprotein of Medof is isolated from non-tumor cells and Hensel does not disclose that SC-1 reacts with non-tumor cells, such as those referenced in Medof. These arguments are not persuasive. Additionally, Applicants reference Hensel et al. (Lab. Invest. 8(11):1553-63, November 2001/ Reference AU of IDS, Paper number 16) to support their arguments.

The facts remain that Medof anticipates claim 1. Applicants have not provided evidence that precludes that Medof's protein does not possess tumor-specific glycostructure and capable of reacting with monoclonal antibody SC-1. Applicants are invited to point out in the specification disclosing evidence or reasoning that contradicts the anticipatory prior art. Applicants have not set forth evidence that precludes Medof's

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protein from having the inherent qualities of the claimed protein. Nor does the Medof reference reflect that the disclosed glycoprotein is not glycosylated or structurally identical to the glycoprotein claimed and would not inherently possess the capabilities of the claimed protein's. Hensel is listed in the rejection in order to clearly establish that DAF is the same as CD55.

The Examiner has reviewed the recently submitted Hensel paper, wherein information is reportedly found on pages 857-858. The paper does not contain the aforementioned page numbers.

5. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Tsuji (U.S. Patent number 5,695,945, issued December 9, 1997), as evidence by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS) is maintained. Claim 2 is cancelled.

Applicants' arguments are based on the same premise as the arguments listed above, as well as the proclamation that the glycoprotein of Tsuji is obtained from non-tumor human blood and does not inherently comprise a tumor-specific glycostructure that interacts with SC-1. This argument is found unpersuasive and maintained for the reasons set forth above.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
August 20, 2002



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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